

Fact Sheet



For Proposed Minor Modification Permitting Action Under 45CSR30 and Title V of the Clean Air Act

This Fact Sheet serves to address the changes specific to this Minor Modification, and shall be considered a supplement to the Fact Sheet corresponding with the Title V operating permit issued on December 12, 2006.

Permit Number: R30-06100033-2006
Application Received: October 25, 2010
Plant Identification Number: 03-54-06100033
Permittee: Mylan Pharmaceuticals Inc.
Facility Name: Chestnut Ridge Plant
Mailing Address: 781 Chestnut Ridge Road; Morgantown, WV 26505

Permit Action Number: MM05 Revised: *Proposed*

Physical Location:	Morgantown, Monongalia County, West Virginia
UTM Coordinates:	589.6 km Easting • 4390.1 km Northing • Zone 17
Directions:	I-79 to Exit 155. Follow signs for WVU. Follow US Route 19 to Coliseum. Turn left onto SR 705 for approximately 1.2 miles. Turn right to stay on SR 705 (Chestnut Ridge Road). Follow for approximately 0.6 miles to plant on left.

Facility Description

Mylan Pharmaceuticals Inc. is a batch pharmaceutical manufacturing company. Mylan purchases raw materials from suppliers and performs various quality control tests on the raw materials. The manufacturing plant mixes, compounds, and formulates pharmaceutical products. The Standard Industrial Classification code is 2834, Pharmaceutical Compounding and Formulating.

The purpose of this modification is to allow Mylan to take credit for VOC destruction in the Regenerative Thermal Oxidizer (RTO) for Fluid Beds 534, 538, 572, 574 – 578, and 580 and to remove authorization for use of a Catalytic Oxidizer (CO).

Emissions Summary

According to the Engineering Evaluation for R13-2068N, the changes to this facility associated with this modification will result in the following Potential to Emit (PTE) decreases:

Pollutant	PTE Decrease (TPY)
NO _x	0.27
CO	0.04
PM	0.01
VOC	11.97
SO ₂	0.01

Title V Program Applicability Basis

With this modification, this facility maintains the potential to emit over 100 tons per year of VOCs. Due to this facility's potential to emit over 100 tons per year of a criteria pollutant, it is required to have an operating permit pursuant to Title V of the Federal Clean Air Act as amended and 45CSR30.

Legal and Factual Basis for Permit Conditions

The State and Federally-enforceable conditions of the Title V Operating Permits are based upon the requirements of the State of West Virginia Operating Permit Rule 45CSR30 for the purposes of Title V of the Federal Clean Air Act and the underlying applicable requirements in other state and federal rules.

The modification to this facility has been found to be subject to the following applicable rules:

Federal and State:	45CSR6	Particulate from combustion of refuse.
	45CSR10	Emission of sulfur oxides.
	45CSR13	
	45CSR30	Operating permit requirement.

Each State and Federally-enforceable condition of the draft Title V Operating Permit references the specific relevant requirements of 45CSR30 or the applicable requirement upon which it is based. Any condition of the draft Title V permit that is enforceable by the State but is not Federally-enforceable is identified in the draft Title V permit as such.

The Secretary's authority to require standards under 40 C.F.R. Part 60 (NSPS), 40 C.F.R. Part 61 (NESHAPs), and 40 C.F.R. Part 63 (NESHAPs MACT) is provided in West Virginia Code §§ 22-5-1 *et seq.*, 45CSR16, 45CSR34 and 45CSR30.

Active Permits/Consent Orders

Permit or Consent Order Number	Date of Issuance	Permit Determinations or Amendments That Affect the Permit (<i>if any</i>)
R13-2068N	1/5/2011	

Conditions from this facility's Rule 13 permit(s) governing construction-related specifications and timing requirements will not be included in the Title V Operating Permit but will remain independently enforceable under the applicable Rule 13 permit(s). All other conditions from this facility's Rule 13 permit(s) governing the source's

operation and compliance have been incorporated into this Title V permit in accordance with the "General Requirement Comparison Table B," which may be downloaded from DAQ's website.

Determinations and Justifications

The following significant changes were made to this Title V permit:

- The emission units table was updated to reflect the most current equipment information.
- The CO was removed from the emission units table.
- Condition 5.1.3. was revised for Fluid Beds 534, 538, 572, 574 – 578, and 580 under RTO control.
- Condition 5.1.4. was revised to have more stringent VOC emission limits for Fluid Beds 534, 538, 572, 574 – 578, and 580 if controlled by the RTO.
- Condition 5.1.5. was revised to lower total combined VOC emissions to the atmosphere from the fluid beds from 110 TPY to 99 TPY after June 1, 2011. Condition 5.2.5., monitoring requirements to demonstrate compliance with 5.1.5, were revised accordingly.
- Conditions 5.2.1. and 7.2.2., monitoring requirements to demonstrate compliance with the cartridge collector collection efficiency under 5.1.3(c) and 7.1.6., were revised.
- All references to the CO were removed from Section 8.0.
- RTO emission limits and operating parameters in Conditions 8.1.3. and 8.1.4. were modified to account for removal of the CO.
- A minimum VOC destruction efficiency of 98% is not included in condition 8.1.5.
- Performance monitoring requirements for the RTO were added as Conditions 8.1.6. and 8.1.7.
- Annual inspection language for the RTO was added as Condition 8.1.8.
- The RTO solvent monitoring requirements in Condition 8.2.3. were modified to apply to only the RTO instead of the RTO and CO.
- Additional performance monitoring requirements were added as Conditions 8.2.4. and 8.2.5. Mylan is required to continuously monitor the RTO combustion chamber temperature and RTO exhaust flow rate. All monitoring equipment must be operated in accordance with manufacturer recommendations.
- Testing requirements were added as Condition 8.3.2. to determine compliance with the minimum VOC destruction efficiency as given under 8.1.5.
- Recordkeeping requirements were added as Conditions 8.4.1. and 8.4.2. This includes records of the occurrence of an excursion of RTO operating parameters outside the ranges as established under 8.1.6.

Non-Applicability Determinations

The following requirements have been determined not to be applicable to the subject facility due to the following:

N/A

Request for Variances or Alternatives

None.

Insignificant Activities

Insignificant emission unit(s) and activities are identified in the Title V application.

Comment Period

Beginning Date: N/A
Ending Date: N/A

All written comments should be addressed to the following individual and office:

Rex Compston
Title V Permit Writer
West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304

Procedure for Requesting Public Hearing

During the public comment period, any interested person may submit written comments on the draft permit and may request a public hearing, if no public hearing has already been scheduled. A request for public hearing shall be in writing and shall state the nature of the issues proposed to be raised in the hearing. The Secretary shall grant such a request for a hearing if he/she concludes that a public hearing is appropriate. Any public hearing shall be held in the general area in which the facility is located.

Point of Contact

Rex Compston
West Virginia Department of Environmental Protection
Division of Air Quality
601 57th Street SE
Charleston, WV 25304
Phone: 304/926-0499 ext. 1209 • Fax: 304/926-0478

Response to Comments (Statement of Basis)

Not applicable.